

## INTERNATIONAL SEARCH REPORT

International application no.

PCT/JP03/12075

## A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl<sup>7</sup> A61K31/155, 45/00, 31/496, 31/5025, 31/522, A61P1/00,  
3/04, 3/06, 3/10, 5/00, 5/50, 43/00

RECEIVED PCT/PTO 17 MAR 2004

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl<sup>7</sup> A61K31/155, 45/00, 31/496, 31/5025, 31/522, A61P1/00,  
3/04, 3/06, 3/10, 5/00, 5/50, 43/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
CAPLUS (STN), CAOLD (STN), REGISTRY (STN), MEDLINE (STN)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/052825 A2 (NOVARTIS A.-G.), 26 July, 2001 (26.07.01),	1-4, 24-27, 30, 32
Y	Page 27 & WO 01/052825 A3 & BR 2001007715 A & US 2003/139434 A1	17-23
X	WO 01/097808 A1 (SMITHKLINE BEECHAM PLC.), 27 December, 2001 (27.12.01),	1-4, 24-27, 30, 32
Y	Pages 3, 12 & EP 1292300 A1 & NO 2002006038 A	17-23
	& BR 2001011800 A & US 2003/166578 A	

 Further documents are listed in the continuation of Box C. See patent family annex.

- \* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search  
03 December, 2003 (03.12.03)Date of mailing of the international search report  
24 December, 2003 (24.12.03)Name and mailing address of the ISA/  
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

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## C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/002560 A2 (NOVO NORDISK A/S), 10 January, 2002 (10.01.02),	1-4,17-27, 30,32
Y	Page 17, 18	17-23
A	& AU 2001068958 A5 & EP 1301187 A2 & BR 2001012123 A & US 2002/161001 A1 & NO 2003000021 A	5-16
X	WO 02/068420 A1 (BOEHRINGER INGELHEIM PHARMA KG.),	1-4,17-27, 30,32
Y	06 September, 2002 (06.09.02),	17-23
A	Page 16 & US 2002/198205 A1 & NO 2003003726 A & DE 10109021 A1	5-16
X	HINKE, S. A., "Metformin Effects on Dipeptidylpeptidase IV Degradation of Glucagon-like Peptide-1." Biochem.Biophys.Res.Commun., 15 March, 2002 (15.03.02), Vol.291, No.5, pages 1302 to 1308	1-4,24-27, 30,32 17-23
X	HINKE, S. A., "On combination therapy of diabetes with metformin and dipeptidyl peptidase IV inhibitors.", DIABETES CARE, (2002, August), Vol.25, No.8, pages 1490 to 1491	1-4,24-27, 30,32 17-23
P,X	WO 03/004496 A1 (NOVO NORDISK A/S), 16 January, 2003 (16.01.03), & US 2003/105077 A1	1-4,17-27, 30,32
P,X	YASUDA, N., "Enhanced secretion of glucagon-like peptide 1 by biguanide compounds.", Biochem.Biophys.Res.Commun., 15 November, 2002 (15.11.02), Vol.298, No.5, pp.779-784	1-4,24-27, 30,32

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**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 29, 31, 33, 34

because they relate to subject matter not required to be searched by this Authority, namely:

Claims 29, 31, 33 and 34 pertain to methods for treatment of the human body by therapy and thus relate to a subject matter which this International Searching Authority is not required, under the provisions of Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

2.  Claims Nos.:

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3.  Claims Nos.:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1, 2, 5 to 26 and 30 relate to a drug comprising a combination of a dipeptidyl peptidase IV inhibitor with biguanide, while claims 3, 4, 27, 28 and 32 relate to a drug potentiating the effect of activated GLP-2 in blood.

The matter common to claims 1 to 28, 30 and 32 resides in being a drug to be used in treating diabetes, etc. As a matter of course, this common matter is not novel without a need for presenting any document and, therefore, cannot be considered as a special technical feature.

Since there is no other matter common to all claims seemingly being a special technical feature, the present case has 2 groups of inventions.

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest  The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

## &lt;Subject of search&gt;

Claim 3 relates to a drug defined by a desired property of "potentiating the effect of activated GLP-2 in blood". Although the active ingredient of the drug according to claim 3 involves any compounds having the above property, it appears that only small part of the claimed compounds are disclosed in the meaning within PCT Article 5 and thus it is recognized that the claim is not supported by the disclosure in the description in the meaning within PCT Article 6.

Even though the common technical knowledge at the point of the application is taken into consideration, the scope of the compounds having the property as the drug active ingredient "potentiating the effect of activated GLP-2 in blood" cannot be specified. Thus, claim 3 do not comply with the requirement of clearness in accordance with PCT Article 6 too.

Concerning claim 3 and claims depending thereon, therefore, the search was made on drugs comprising the compounds specified in claims 5 to 23 combined with biguanide wherein the relationship between the effect of "potentiating the effect of activated GLP-2 in blood" and drugs are specifically stated in the description.